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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,261	05/29/2001	Gerald V. Quinnan JR.	044508-5001	2761

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EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,261

Applicant(s)

QUINNAN ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-44 and 47-64 is/are rejected.
- 7) ☒ Claim(s) 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

The request filed on 11/12/03 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/762,261 is acceptable and a RCE has been established. An action on the RCE follows.

The examiner sincerely appreciates the chart applicant provided on page 6 of the response that points to support for the newly pending claims.

Specification

The amendment filed November 12, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Applicant states in paragraph 3 that the deduced amino acid sequence from the original sequence is AAG, which corresponds to a lysine. In paragraph 3, applicant states that in subsequent experiments using the originally disclosed sequence, it was realized that the amino acid sequence corresponding to position 650 in SEQ ID NO: 1 should have been assigned as a serine. However, this discovery is not supported in the original disclosure as filed. Applicant has not submitted sufficient evidence showing possession of SEQ ID NO: 1 with a serine at position 650 instead of a lysine. In paragraph 5, applicant discusses further sequencing analysis for confirmation of the amino acid residue. The results of this sequencing experiment indicated a serine (AGC) at position 650. However, there is no indication that the sample of the original

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cDNA discussed in paragraph 5 was taken from the same sample that was used to disclose the sequence of SEQ ID NO: 1 in the originally filed application.

Therefore, it is determined that the original disclosure has support for amino acid position 650 corresponding to a lysine. Applicant is required to cancel the new matter added by the amendment.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 37-63 been renumbered 38-64.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38-44 and 47-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires that the protein or fragment is at least 37 amino acids long as comprises SEQ ID NO: 24, "or conservative amino acid substitutions at positions 3 to 9 of said amino acid sequence". It cannot be determined from the claim which sequence comprises the substitutions.

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Is this phrase referring to the “37 amino acids” or SEQ ID NO: 24? This rejection affects all dependent claims.

Claim 43 is drawn to an HIV envelop protein or fragment thereof “consisting essentially of” an amino acid sequence. The metes and bounds of “consisting essentially of” is not defined by the claims or the specification. Applicant points to page 3, lines 8-10 and page 6, lines 17-22 for support of the claim. However, it cannot be discerned whether the fragment in the claim may contain additional sequences, or if applicant intends to claim only the fragment recited. Since there is no clear definition provided in the specification for ingredients that would materially affect the sequence claimed “consisting essentially of” is being interpreted as “comprising”. See the MPEP § 2111.03. This rejection also affects dependent claims 51-54.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-44 and 47-64 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass an isolated HIV envelope protein or fragment thereof, of at least 37 amino acids comprising SEQ ID NO: 24, “or conservative amino acid substitutions at positions 3 to 9 of said amino acid sequence. Applicant points to page 7, lines 20-24 for support for this limitation. However, the examiner is unable to locate implicit or explicit support for the

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conservative amino acid substitutions at between the specific range of amino acids claimed.

Therefore, this language appears to constitute new matter. The disclosure does not disclose a representative number of species to represent the number of sequence species claimed.

Applicant is required to either point to where support can be found in the original disclosure or cancel the new matter.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, there is no identification of any particular portion of SEQ ID NO: 24 that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, given that the specification has only described SEQ ID NOs: 1 and 2.

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Therefore, only isolated proteins and fragments comprising the amino acid sequence set forth in SEQ ID NOs: 1 and 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

In addition, claim 43 recites indefinite claim language “consisting essentially of” without defining the metes and bounds of what is intended by the phrase. There is no description provided that would allow one of skill in the art to readily identify which materials would affect the sequence claimed or other essential physical characteristics of the instant protein without undue experimentation. One skilled in the art to would be unable to recognize ingredients that are intended to be excluded from the “consisting essentially of” language. Therefore, it is concluded that the specification does not reasonably convey possession of the full genus of materials claimed. The rejection of claim 43 also affects claims 51-54.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-40, 47, 49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Geneseq database accession no: AAR77770, submitted September 1995 in WO 94/229339-A1.

The claims are drawn to an isolated HIV envelope protein fragment of at least 37 amino

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acids comprising SEQ ID NO: 24, or has conservative amino acid substitutions at positions 3-9 of said amino acid sequence.

The sequence of geneseq database accession no: AAR77770A comprises SEQ ID NO: 24 and is 65 residues in length and comprises all of the structural features necessary to induce cross-neutralizing antibodies *in vitro*, see the sequence alignment provided. In addition, the brief description of the sequence indicates that it is synthetically produced for the treatment of HIV.

Claims 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by SPTREMBL database accession no: Q71538 submitted November 1, 1996 by Strunnikova et al.

See the summary of claims 38-40 above.

The amino acid sequence of Q71538 is 92 residues long and has 100% sequence similarity with SEQ ID NO: 24 comprising conservative amino acid substitutions between position numbers 3 to 9.

Allowable Subject Matter

Claims 45 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Patent Examiner, 1648